

REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed November 12, 2008. Claims 36 and 38-57 were pending and rejected in view of cited art.¹ Claim 50 is amended. Claims 36 and 38-57 remain pending in view of the above amendments.²

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

B. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. §102(B)

The Office Action rejected claims 50 and 51 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,545,178 (*Kensey*). Claims 50, 51, and 57 were rejected under U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,228,096 (*Marchand*). Because neither *Kensey* nor *Marchand* disclose, teach, or suggest each and every element of the rejected claims, Applicant respectfully traverses this rejection in view of the following remarks.

The Office Action asserted that *Kensey* and *Marchand* "disclose[] an apparatus for facilitating sealing of a puncture . . . the apparatus comprising a bar having proximal and distal ends and a first eyelet coupled to the bar" (Office Action, page 2). In direct contrast, independent claim 50 recites, in part, "a bar having proximal and distal ends, a first bore

¹ Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

² Support for the claim amendments and/or new claim(s) can be found throughout the specification and drawings as originally filed.

extending laterally therethrough, and a first eyelet coupled to the bar; and a filament having a first free end and a second free end, the filament being slidably disposed through the first eyelet and the first bore . . .” (emphasis added). Neither *Kensey* nor *Marchand* include both the “first bore . . . and a first eyelet” as claimed in independent claim 50.

Since *Kensey* and *Marchand* do not teach the apparatus of independent claim 50, and associated dependent claims 51 and 57, Applicant respectfully requests that the rejection under 35 U.S.C. § 102(b) be withdrawn.

II. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejected claim 56 under 35 U.S.C. § 103(a) as being unpatentable over *Marchand*. Claims 52 and 53 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Marchand* in view of U.S. Patent No. 6,506,197 (*Rollero*). Claims 54 and 55 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Marchand* in view of U.S. Patent No. 5,810,884 (*Kim*). Claims 36, 38-40, 44, and 48 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Reissue Patent No. Re. 36,974 (*Bonutti*) in view of *Kim*. Claims 41-43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bonutti* in view of *Kim* as applied to claim 36 and further in view of U.S. Patent No. 5,411,520 (*Nash*). Claims 45-47 and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bonutti* in view of *Kim* as applied to claim 36 and further in view of *Rollero*. Applicant respectfully traverses.

Marchand discloses an “instrument and method for manipulating an operating member coupled to suture material while maintaining tension on the suture material” (Title). With the suture anchor, including the suture through the eyelet, in “the transverse orientation, [the] suture anchor 100 bridges the hole formed in tissue T” (Col. 5, ll. 57-58). With the suture anchor being unable to “pass back through the hole formed in tissue T . . . [the] suture material S is fixed to tissue T and soft tissue or the like can be attached to the suture material in a known manner” (Col. 5, ll. 59-62). In this manner, it appears that the suture remains attached to the anchor to enable “soft tissue or the like . . . [to] be attached to the suture material.” *Id.*

Similarly, the identified suture anchors of *Kim* and *Rollero* include sutures that remain attached following deployment. In contrast, and as recited in independent claim 50, the apparatus includes “a filament having a first free end and a second free end, the filament being removably and slidably disposed through the first eyelet and the first bore, the bar being removable from and slidable relative to the filament.”

Accordingly, Applicant respectfully submits that independent claim 50, and associated dependent claims 51-57, are neither taught nor suggested by *Marchand*, *Kim*, or *Rollero* whether alone or in combination. Applicant therefore respectfully requests withdrawal of the rejection of claims 52-56 under Section 103.

Turning to the rejection of claims 36 and 38-48 over *Bonutti* in view of *Kim* and optionally further in view of *Nash* or *Rollero*, the Office Action asserted that "*Bonutti* discloses a delivery sheath in which the filament and bar are disposed but fails to disclose a sharpened tip at the distal end." (Office Action, page 4.) To overcome this deficiency, the Office Action combines the teaching of *Kim* ("that it is well known in the art to include a sharpened tip (48)" (Office Action, page 5)) with that of *Bonutti*. Applicant respectfully disagrees with the combination because *Bonutti* appears to have contemplated the use of the suture anchor for soft tissue use and neither taught nor suggested the use of "a delivery sheath having . . . a sharpened tip at the distal end" as claimed in independent claim 36. Specifically, "[i]n jointing soft tissue to soft tissue, it is preferable to insert the anchor directly through the soft tissue, *not into an opening in the tissue*. Thus, the anchor may have a slightly sharpened or pointed distal end (tip) to push through the tissue layers." (Col. 8, ll. 37-41) There would be no reason to first puncture the tissue with a delivery sheath because the anchor itself is sharpened to penetrate the tissue.

Further, *Bonutti* describes modifications to the insertion tool, but Applicant has not found any suggestions or teachings to include a sharpened tip, rather *Bonutti* indicates that "both the anchor and the insertion tool may be curved, or may be made of an elastic material in order to be able to be pushed over a curved K-wire" (Col. 8, ll. 41-43). There would, therefore, be no reason to combine the sharpened tip of *Kim* with the device of *Bonutti* and any combination would appear to change the principle of operation of *Bonutti* by eliminating the need for the "sharpened or pointed distal (tip)" of the anchor and changing the "insertion guide flange portion 94" or the "tapered distal end portion 212" to a sharpened tip. (*see* MPEP 2143.01).

Neither *Nash*, cited as disclosing "that it is old and well known in the art to include a tensioning device" nor *Rollero*, which was cited as disclosing "that it is old and well know in the art to include a plurality of attachment points" overcome the deficiency of *Bonutti* or *Kim*. Therefore, Applicant respectfully submits that independent claim 36 and associated dependent claims 38-49 are neither taught nor suggested by *Bonutti* or *Kim*, whether alone or in combination. Furthermore, dependent claims 39, 40, and 44 are allowable for at least the same reasons.

C. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 12th day of March, 2009.

Respectfully submitted,

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